REMARKS

Claims 1-9 are currently pending. Claim 1 has been amended to indicate that in the claimed massage apparatus, fluid is pumped and flows "in only a single direction through the array, the direction being from the input ports to the output ports" This limitation is apparent from the disclosed arrangement found in FIG. 5 and on page 4, lines 8-11 and page 10, lines 1-14 of the specification. Claims 2 and 3 have been amended to indicate that the reservoir means and electrical energy means are implantable. Support for this amendment is found in the original claims as well as page 4, lines 12 to page 5, line 4. Claim 8 has been amended to independent form and to indicate that Bourdon tube is elastic. Support for this amendment is found on page 10, line 18 to page 11, line 7 of the specification. Claim 9 has been added to claim an implantable cardiac massage apparatus having "a helically wound tubing formed into an array" wherein "fluid is pumped, and flows, in only a single direction through the array, the direction being from the input ports to the output ports." Support for this claim is found in FIG. 1 and page 6, lines 1-33 of the specification. Applicants respectfully submit that no new matter has been added by these amendments.

The specification of the application has been amended to indicate that the Bourdon tube is made from an elastic material. Support for this amendment is found in Van Nostrand's Scientific Encyclopedia, 8th edition (1995) which was originally incorporated by reference in the application, and the ordinary and plain meaning of the term "Bourdon Tube" to one of ordinary skill in the art as indicated in the Coleman Declaration. Applicants respectfully submit that no new matter has been added by these amendments.

Claims 1-8 of the application stand variously rejected. Claims 2-3 stand rejected under 35 USC § 101 as being directed toward non-statutory subject matter. Claims 1-8 stand rejected as being anticipated under 35 USC § 102(e) as being anticipated by U.S. Patent No. 6,602,182 issued to Milbocker (hereinafter "Milbocker"). Applicants respectfully traverse these rejections for at least the following reasons.

Rejections under 35 USC § 101

Claims 2-3 stand rejected under 35 USC § 101 as being directed toward non-statutory subject matter. The Examiner contends that the language "implanted" makes the claims inferentially recite the body. Applicants have amended claims 2 and 3 to change the word to

"implantable". Applicants respectfully submit that claims 2 and 3 are now compliant with 35 USC § 101, and request that the rejection to these claims be withdrawn.

Rejections under 35 USC § 102(e) over Milbocker

Claims 1-8 stand rejected as being anticipated under 35 USC § 102(e) over Milbocker. The Manual of Patent Examining Procedure "MPEP" states that, in order to anticipate a claim, a reference must teach every element of the claim:

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)." See MPEP § 2131

Applicants submit that the Milbocker reference fails to disclose each and every element of claims 1-8.

Claim 1 of the application (on which claims 1-7 depend), has been amended to recite:

> "An implantable cardiac massage apparatus for providing assistance to a heart having an apex and a base, the apparatus comprising:
>
> a chamber array, the array comprising a series of spaced-apart, fluidically coupled chambers, the array having fluid input and output ports, and the chambers defining an inside surface which closely conforms to the external surface of a heart and;
>
> pressure regulator means, the pressure regulator means being fluidly coupled to the array input port and output port, the pressure regulator means also being fluidically coupled to;
>
> pump means, the pump means and the pressure regulator means being electronically coupled to;
>
> controller means, the controller means being adapted to actuate the pump means and the pressure regulator means so that fluid is pumped, and flows, in only a single direction through the array, the direction being from the input ports to the output ports, the fluid is pumped substantially continuously by the pump means to the input port and the pressure regulator means intermittently inflates and deflates the chambers starting at the apex of the heart to create a rhythmic message of the heart from its apex to its base thereby substantially imitating the natural contraction of the heart, the controller means being further adapted to receive sensor information input from;

a cardiac activity/sensor means, the cardiac activity/sensor means being adapted to sense cardiac activity and input sensor information to the controller means." See claim 1, emphasis added.

The Milbocker patent is directed towards a cardiac assistance system having multiple fluid plenums. While the fluid tubes of Milbocker are arranged so that the tubes are oriented with their axis running from the apex to the base of the heart, the fluid input and output to the tubes is a single input/output port located near the apex of the heart. FIG. 11 of Milbocker shows the inflation coupler 305 to be located at only one end of the tubes. See col 17, lines 3-5 of Milbocker. FIG. 16 of Milbocker shows a single input/output port for the plenum array. See FIG. 16 of Milbocker, with notations, below:

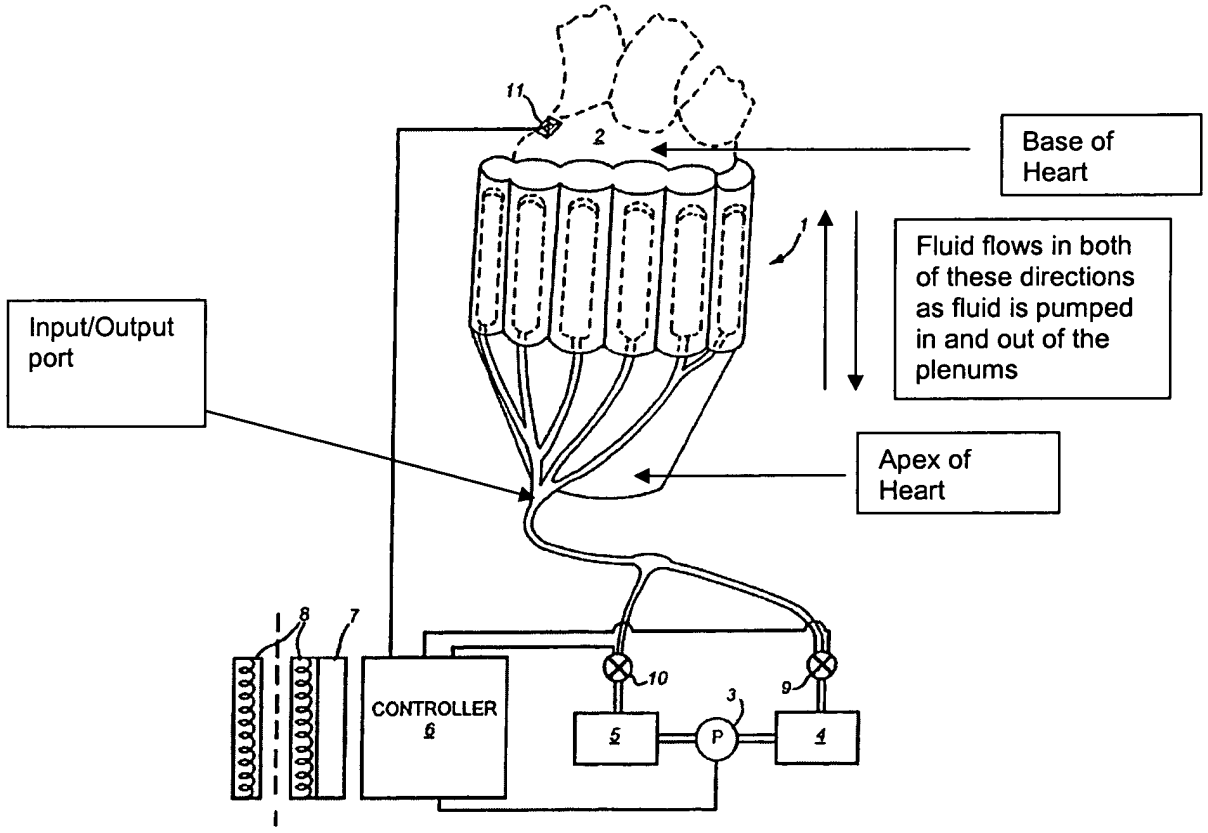


FIG. 16 of Milbocker - Annotated

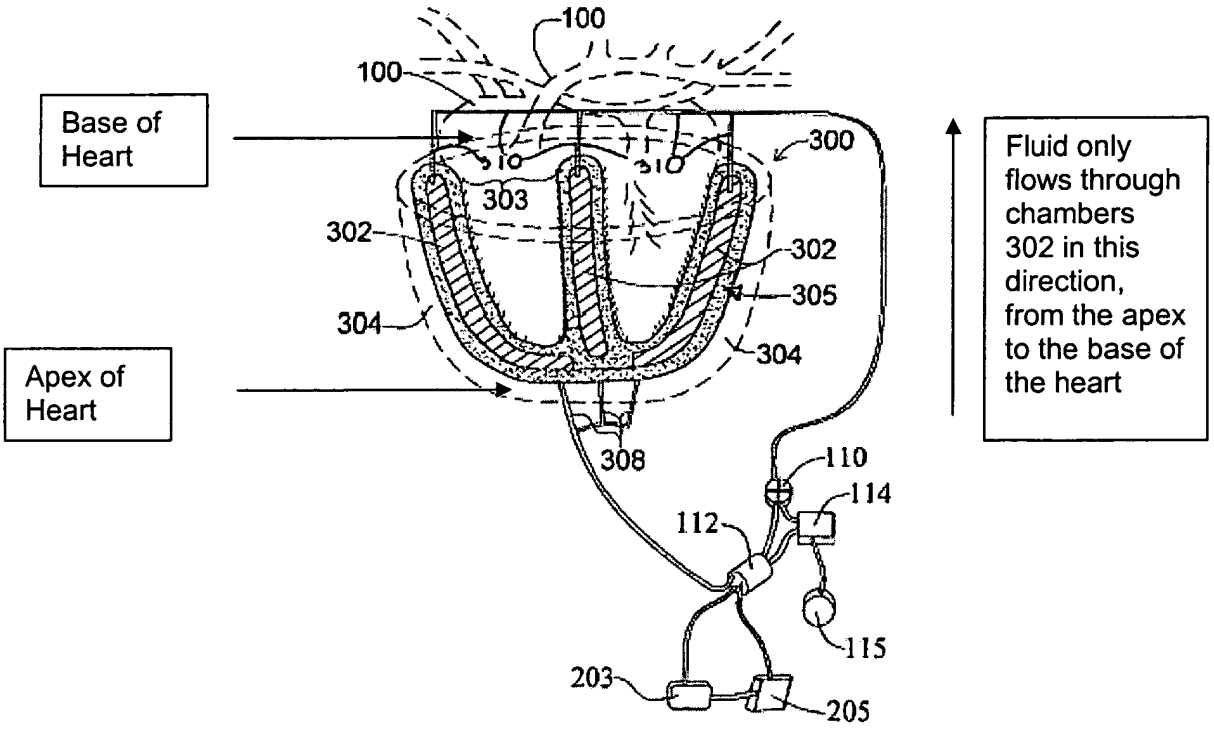
Milbocker discloses that the cardiac assistance device of the invention includes a:

"mechanical device or energy converter for periodically pumping fluid from the storage plenum to the pumping unit and thus attaining a pressurized state in the pumping unit, said energy converter pumping toward the pumping unit during systole and pumping from the pumping unit during diastole." See col. 6, lines 20-25 of Milbocker. Also see col. 7, lines 15-22 and col. 7, lines 30-36 of Milbocker.

The Milbocker invention, therefore, discloses a cardiac assistance device wherein the plenums are actively inflated by a bidirectional pump. The input/output of the fluid that goes to the to the plenums goes through a single input/output port located near the apex of the heart, with the pump actively pumping fluid in one direction into the tubes from the apex to the base of the heart, and then actively pumping fluid from the tubes, in an opposite direction, so that the fluid in the tubes flow from the base of the heart to the apex.

In contrast, as set forth in claim 1 as amended, and shown in FIG. 5 of the present application, the presently claimed cardiac massage apparatus of the present invention has separate input and output ports for the chamber array wherein fluid is "pumped, and flows, in only a single direction through the array, the direction being from the input ports to the output ports." See claim 1, as amended.

FIG. 5



This claimed structure only provides for the pumped fluid inflating the chambers to flow in a single direction, from the apex of the heart to the base of the heart. Claim 1 sets forth that the pumped fluid, regulated by the pressure regulator means, "inflates and deflates the chambers starting at the apex of the heart to create a rhythmic message of the heart from its

apex to its base." The specification elaborates that with such a structure, fluid enters into the input tubes 308 and then:

> "fluid flows from the apex of heart 100 toward its base, pulsatile fluid emerging from fingers 302 into return connector or output connectors 310 to be returned to pressure regulator 110 for reuse." See page 10, lines 11-13 of the speciation.

It is significant that the claimed structure of claims 1-7 allows for inflation of the tubes in a single direction, from the apex of the heart to the base of the heart. This apex to base contraction substantially imitates the natural contraction sequence of the heart. Furthermore, as detailed in the Coleman declaration, the one way apex to base contraction prevents the blood from within the heart to back-flow into the ventricles. Dr. Coleman states:

> "With the present invention as set forth in claim 1, the input and output ports are separate from each other (i.e. they are not the same opening). Furthermore, fluid is pumped, and flows, in one direction. The fluid flows from the input port to the output port in a continuous fashion, the chamber array being inflated (and subsequently deflated) from the apex to the base of the heart. This upward-only movement by the chamber array prevents blood from within the heart to back-flow into the ventricles. During diastole, blood fills the ventricles. During systole, the chamber array of the present invention inflates, starting from the apex location, and contracts the heart muscle to push blood up through the aorta. With the invention set forth in claim 1, the chamber array provides no downward pull to cause the blood to back-flow into the ventricles in operation of this invention." See paragraph 9 of the Coleman Declaration.

The claimed structural features of claims 1-7, therefore, provide a clear and beneficial advantage over the cited prior art. One of the advantages being the "fluidically coupled chambers" having "input and output ports" wherein "fluid is pumped, and flows, in only a single direction through the array, the direction being from the input ports to the output ports" so that the chambers are inflated "starting at the apex of the heart to create a rhythmic message of the heart from its apex to its base " See claim 1 as amended.

For the structure disclosed by Milbocker to work it requires a bidirectional fluid flow, one from apex to base for inflation of the tubes, and one from base to apex for deflation of the tube.

Applicants therefore respectfully submit that the Milbocker patent fails to disclose all of the limitations of claims 1-7 as amended, specifically, a cardiac massage apparatus having "input and output ports" wherein "fluid is pumped, and flows, in only a single direction through the array, the direction being from the input ports to the output ports" (See claim 1). As the reference fails to teach all of the limitations of claims 1-7, it fails to anticipate the claims.

Applicants, therefore, respectfully request the Examiner withdraw the rejections to claims 1-7 on this ground.

Claim 8, as amended, recites:

> "An implantable cardiac massage apparatus for providing assistance to a heart having an apex and a base, the apparatus comprising:
>
> a chamber array, wherein the chamber array comprises elastic Bourdon tubes, the array comprising a series of spaced-apart, fluidically coupled chambers the array having fluid input and output ports, and the chambers defining an inside surface which closely conforms to the external surface of a heart and;
>
> pressure regulator means, the pressure regulator means being fluidly coupled to the array input port and output port, the pressure regulator means also being fluidically coupled to;
>
> pump means, the pump means and the pressure regulator means being electronically coupled to;
>
> controller means, the controller means being adapted to actuate the pump means and the pressure regulator means so that fluid is pumped by the pump means to the input port and the pressure regulator means intermittently inflates and deflates the chambers starting at the apex of the heart to create a rhythmic message of the heart from its apex to its base thereby substantially imitating the natural contraction of the heart, the controller means being further adapted to receive sensor information input from;
>
> a cardiac activity/sensor means, the cardiac activity/sensor means being adapted to sense cardiac activity and input sensor information to the controller means." See claim 8, emphasis added.

The cardiac massage apparatus of claim 8, therefore, has elastic tubes (Bourdon Tubes) which are coupled to fluid input and output ports. Claim 8 also indicates that while the fluid is pumped to the input port by the pump (i.e. in one direction), the pressure regulator, along with the elastic force provided by the Bourdon tubes, allows for the deflation of the chambers. The specification of the application indicates that when the device is operated:

> "The cup-shaped elastic members 403 are substantially radially rigid and hence help the fingers 402 to compress the heart 100 effectively when pulsatile input of fluid from pump 112 (via pressure regulator valve 110 and input tube or input connector 408) cause the elastic fingers 402 to be displaced inwardly thereby massaging heart 100. The pressure generated due to the fluid flow from the pump 112 helps the heart to be massaged from the apex to its base in accordance with the invention. When pressure regulator 110 changes the direction of fluid flow upon the signal received from the microprocessor 114, the backward fluid flow will contract the Bourdon tube fingers outwardly to release

> the pressure from the heart 100. The outflow of the fluid from the fingers 402 will return through the output connector 409 and pressure regulator valve 110) back into the pump 112 and reservoir 205 for reuse. See page 7, line 25 to page 11, line 4, emphasis added.

The apparatus of claim 8, therefore, has elastic tubes that inflate when filled with fluid. When the pressure regulator changes the direction of fluid flow, the elastic fingers contract and force the fluid out the output connector. Dr. Coleman explains in his declaration the basic workings of a Bourdon tube device:

> "Bourdon tubes are well known to those of skill in the art. A Bourdon tube is a curved and partially flattened tube that tends to straighten out in proportion to pressure. The unique feature of this is that the material properties of the Bourdon tube in the non-pressurized state return to the "relaxed" or "non-compressive" state. Therefore, in the present invention, when the Bourdon tube is in a pressurized state from the input of fluid from pump, the tubes contract the heart, and when they are not in a pressurized state, the tubes recoil away from heart, facilitating the refilling of heart passively. Thus fluid is only actively pumped by the pump of the invention in one direction. Once the pump stops, the Bourdon tubes are in a non-pressurized state and recoil from the heart, sending the fluid back through an output tube." See paragraph 12 of the Coleman Declaration.

In contrast, the Milbocker contains no disclosure of any Bourdon tube arrangement. Milbocker discloses the use of a balloon like plenum, preferably a two plenum system, wherein:

> "the inflation fluid and a bi-directional constant pressure pump is used to both inflate and evacuate the heart assist device." See col. 5, lines 40-42.

The use of an active pump to deflate the plenum of the Milbocker apparatus is also discussed at col. 6, lines 20-25, col. 7, lines 15-22 and col. 7, lines 30-36 of Milbocker.

The Milbocker patent, therefore, discloses a system wherein a pump is required to both inflate and deflate the plenum. In contrast, the cardiac massages apparatus of claim 8 does not require a pump to deflate the chambers, rather, the deflation can be obtained simply by a signaling to the pressure regulator to allow the backflow of liquid to the regulator by the pressure provided by the contracting Bourdon tubes. Such an arrangement is not taught by the Milbocker reference.

The structure of the cardiac massage apparatus of claim 8 is significant in that it allows deflation of the chambers without the active pumping of a pump. Therefore, in case of pump failure, the chambers would still deflate and not constrict the heart. Such is not the case with the structure taught by Milbocker. In fact, Milbocker discloses that their system that would

require manual deflation by means of a needle inserted into the cardiac assist system implanted in the patient. Milbocker recites the use of:

> "...a subdermal port for draining the pumping unit in the event of failure of the hydraulic pumping capacity. Such a subdermal port can be accessed through a skin puncture with an array of 15 gauge needles. The procedure would involve extraction of hydraulic fluid using a syringe. The result would be collapse of the wrap." See col. 26, lines 27-33.

As discussed in the Coleman declaration, this structure presents a clear disadvantage, from the presently claimed structure utilizing Bourdon tubes:

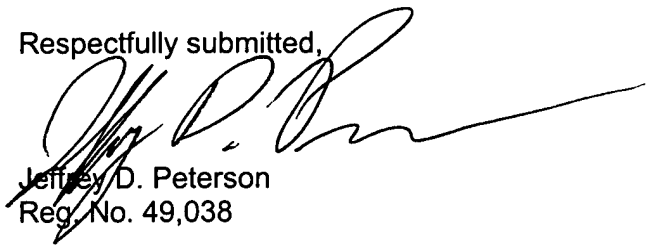
> "In contrast to the cardiac massage apparatus set forth in claim 8, the Milbocker patent discloses an arrangement where fluid is actively pumped into, and out of, the chambers. Milbocker thus teaches the use of a bi-directional pump which is completely different than the Bourdon tube concept. This is of important significance in that in the event of failure of the pump, the tubes must be drained so as not to encumber the natural function of the heart. The solution of Milbocker is to use a subdermal port for draining the pumping unit in the event of failure of the hydraulic pumping capacity of the heart. Milbocker teaches that the port can be accessed through a skin puncture with an array of 15 gauge needles. This again is totally different than our device in which during device failure the Bourdon tube returns to its natural state, which is away from the heart. One experienced in the art can readily see that the Millbocker patent requires that recipients of the Millbocker device are required to travel wherever they go with an assortment of syringes and 15 gauge needles in the event of device failure where as our device that is not necessary." See paragraph 13 of the Coleman declaration.

It is clear from the above, that the Milbocker reference fails to disclose a cardiac massage apparatus having "elastic Bourdon tubes", a pump that pumps fluid "to the input port" (i.e. in one direction) and a "pressure regulator means" that "intermittently inflates and deflates the chamber". As the Milbocker reference fails to teach all of the limitations of claim 8, as amended, the reference fails to anticipate claim 8. As the reference fails to anticipate claim 8, Applicants respectfully request that the rejection to claim 8 be withdrawn.

SUMMARY

Based on the foregoing, Applicants respectfully submit that the present application is in condition for allowance, and a favorable action thereon is respectfully requested. Should the Examiner feel that any other point requires consideration or that the form of the claims can be improved, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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